

### **REMARKS**

Applicants thank the Examiner for entering applicants' amendments dated April 19, 2010.

Applicants have amended claims 21, 24, 27, 30, 33, 36, 38, 48, and 50. Applicants have also canceled claims 20 and 51. Following entry of these amendments, claims 21-40, 46, 48, and 50 will be pending in this application and claims 1-20, 41-45, 47, 49, and 51 will be canceled. Of the pending claims, claims 21-40 are withdrawn. Claims 21-35 are subject to rejoinder.

#### **The Claim Amendments**

Applicants have canceled claims 20 and 51.

Applicants have amended claim 50 to recite the specific structures of each claimed compound. Support for this amendment can be found in the application as filed at, *e.g.*, Table 1 on pages 18-39.

Applicants have amended claims 21, 24, 27, 30, and 33 to depend from claims 46 and 50, instead of now-canceled claims 20 and 51. Applicants have also amended claims 36, 38, and 48 to depend only from claim 46, instead of now-canceled claim 20. Support for these amendments can be found in the application as filed at, *e.g.*, pages 9-17 and pages 45-46.

None of these amendments adds new matter.

Applicants make these amendments and claims cancellations expressly without prejudice and without waiver of their right to file for and obtain claims directed to the canceled subject matter in applications claiming priority benefit from this application.

## **THE REJECTIONS**

### **35 U.S.C. § 112, First Paragraph – Written Description**

The Examiner has rejected claims 20, 46, 48, and 50-51 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner alleges that the recitation of claim 46 that “two adjacent groups selected from either R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, and R<sub>5</sub> or from R<sub>7</sub>, R<sub>8</sub>, R<sub>9</sub>, R<sub>10</sub>, and R<sub>11</sub>, are taken together with the carbon atoms to which they are bound to form a 5 to 6 membered aromatic carbocyclic ring or heterocyclic ring” is not supported in the specification. The Examiner further asserts that page 14, lines 15-20 of the specification is contrary to what applicants have in their amendments. Applicants traverse.

First, applicants have canceled claims 20 and 51, thus rendering moot the rejection with respect to those claims.

Second, the application as filed provides ample written description for claims 46 (from which claim 48 depends) and 50, both of which recite a *pharmaceutical composition* comprising the claimed compound and a pharmaceutically acceptable carrier, adjuvant or vehicle for oral or injectable administration. The application as originally filed clearly states that the excluded compounds as recited on page 14, lines 15-20 are “not known or suggested to inhibit IMPDH, nor have they ever been known or suggested to be formulated with a pharmaceutically acceptable adjuvant, carrier or excipient.” (see page 14, lines 21-26). The application as filed states that the excluded compounds are *not* excluded from aspects of this invention which involve any *methods or compositions* disclosed in the application (see page 14, lines 27-29). Further, the application as filed fully discloses a variety of specific compounds as examples of the claimed genus in claim 46. Those compounds were synthesized and demonstrated to exhibit the activity of

inhibiting inosine-5'-monophosphate dehydrogenase (IMPDH) (see, *e.g.*, Example 6 and Table 2 on pages 61-63 of the specification). Therefore, the specification as filed provides the requisite description for the full scope of claims 46, 48, and 50.

For the above reasons, applicants request that the Examiner withdraw the written description rejection.

**35 U.S.C. § 112, First Paragraph – Enablement**

The Examiner has rejected claims 20 and 51 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Examiner alleges that these claims are couched in terms of composition claims, but that the intended use appears to be every disease possible.

Applicants traverse. Applicants submit that these claims are composition claims – not method of treatment claims. The application as filed teaches how to make and use these compositions (see, *e.g.*, page 45, line 8 to page 51, line 31). However, solely to expedite prosecution and without acquiescing as to the propriety of the rejection, applicants have canceled claims 20 and 51, thus rendering moot the rejection with respect to those claims. Accordingly, applicants request the Examiner withdraw the enablement rejection.

**35 U.S.C. § 112, Second Paragraph – Indefiniteness**

The Examiner has rejected claim 50 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The Examiner has suggested that applicants should clearly write the structures of each compound they want to claim.

Applicants have amended claim 50 to include the structures of each claimed compound, as suggested by the Examiner, thus obviating this rejection. Accordingly, applicants request the Examiner withdraw this indefiniteness rejection.

**35 U.S.C. § 102 (b) – Anticipation**

The Examiner has rejected claims 20, 46, 50, and 51 under 35 U.S.C. § 102(b) as allegedly being anticipated by Buu-Hoi *et al.* (Bulletin de la Societ Chimique de France, pp128-136, (1947)). Pointing to page 135, section IX of Buu-Hoi, the Examiner alleges that it discloses the claimed compositions.

Applicants traverse. First, as discussed above, applicants have canceled claims 20 and 51, thus rendering moot the rejection with respect to those claims. Second, applicants submit that claims 46 and 50 recite a *pharmaceutical composition* that requires a compound as claimed and a *pharmaceutically acceptable carrier, adjuvant, or vehicle* for *oral or injectable administration*. This invention teaches that the claimed pharmaceutical compositions may be advantageously used as therapeutic agents for IMPDH mediated processes (see, *e.g.*, page 1, lines 9-12 of the specification). Moreover, the application discloses that the claimed pharmaceutical compositions are useful as IMPDH inhibitors and can be used for the treatment or prophylaxis of transplant rejection and autoimmune disease (see, *e.g.*, page 6, lines 4-24 of the specification).

Buu-Hoi discloses the preparation of 8 specific compounds. Buu-Hoi does not disclose that these compounds are useful as part of a pharmaceutical composition as recited in the claims 46 and 50 of the present application. Further, Buu-Hoi does not disclose that the compounds referred to therein could be used or formulated for oral administration or administration by injection. Because Buu-Hoi does not teach each and every element of claims 46

and 50, it does not anticipate those claims. Accordingly, applicants request that the Examiner withdraw this anticipation rejection.

**Rejoinder of Withdrawn Method of Use Claims 21-35**

Applicants submit that composition claims 46, 48, and 50 are in condition for allowance. Applicants request that the Examiner rejoin withdrawn method claims 21-35, all of which depend, directly or indirectly, from those composition claims.

**CONCLUSION**

Applicants request that the Examiner consider the above remarks and amendments, withdraw the outstanding rejections, and allow the pending claims.

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